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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,180	10/28/2003	William Travis Young	33386	2749

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,180	YOUNG ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11 and 13-16* is/are rejected.

7)☒ Claim(s) *8 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This general action is in response to the application filing date of 10/28/2003

Claim Objections

1. Claims 8 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Popescu et al (U.S.P.N. 5,464,580).

With respect to claim 1, the Popescu reference teaches the following steps in ethylene sterilization of medical items (col.1, lines 6-11): conditioning items by placing them into a chamber then evacuate the chamber then introduce steam then re-evacuate again (col.5, lines 22-32), injecting ethylene gas into the chamber (col.5, lines 40-41), introducing an overpressure nitrogen gas into the chamber (col.5, lines 37-40), holding the items in the chamber until sterilization is reached (col.5, lines 43-45) and degassing the items (col.6, lines 35-44).

With respect to claims 2-4, 6 and 13, the Popescu reference teaches the following: heated inert gas is nitrogen (col.5, lines 54-56), sterilant is ethylene gas (col.5, lines 40-41), evacuating the chamber after holding the product in the chamber (col.5, lines 49-51) and pulsing in heated inert gas into the chamber (col.6, lines 12-35), degassing the items by evacuating the chamber (col.6, lines 19-21), pressurizing the chamber with 3 to 50 inches of mercury with nitrogen gas (21-22), repeating until the items are degassed (col.6, lines 19-32) and the rate of degassing is in the range of 0.1 to 0.5 inches per minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) in view of Vera et al (U.S.P.N. 6,440,364) and further in view of Joslyn (U.S.P.N. 4,770,851).

With respect to claim 14, the Popescu reference teaches the following steps in ethylene sterilization of medical items (col.1, lines 6-11): conditioning items by placing them into a chamber then evacuate the chamber then introduce steam then re-evacuate again (col.5, lines 22-32), injecting ethylene gas into the chamber (col.5, lines 40-41), introducing an overpressure nitrogen gas into the chamber (col.5, lines 37-40) at a pressure of 13 inches of mercury (col.5, lines 38-40), holding the items in the chamber until sterilization is reached (col.5, lines 43-45), evacuating the chamber to vacuum pressure values less than 1-3 inches of mercury and pulsing in heated nitrogen into the chamber (col.5, lines 53-55). The Popescu reference fails to teach evacuating to a pressure of 1 to 3 inches of mercury and injecting the chamber with warm air. The Vera reference, which is in the art of ethylene gas sterilization, teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48) and injecting filtered air into the chamber

(col.5, lines 5-11). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Popescu reference by evacuating the chamber to pressure of 1 to 3 inches of mercury to provide an effectively low pressure sufficient to effectively remove air from the chamber (the Vera reference, col.3, lines 44-46) and to flush the chamber with filtered air in order to perform the degassing cycle into separate chambers (the Vera reference, col.5, lines 1-7).

With respect to claim 14, the Vera reference teaches injecting filtered air into the chamber (col.5, lines 5-11), but fails to teach injecting warm air; however, the Joslyn reference, which is in the art of ethylene sterilization, teaches injecting warm air into the chamber (col.6, lines 40-43). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Popescu reference by adding a heated air injection step as taught by the Joslyn reference in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (table 2, columns 3-4).

With respect to claim 15, the Popescu reference discloses that the evacuating rate during the degassing cycle is in the range of 0.1 to 0.5 inches per minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min), but fails to teach evacuating to a pressure of 1 to 3 inches of mercury. The Vera reference teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method

of the Popescu reference by evacuating to between 1 to 3 inches of mercury as taught by the Vera reference in order to effectively remove air from the chamber and the package (col.3, lines 44-46).

With respect to claim 16, the Popescu reference teaches repeating the step of pulsing heated nitrogen into the chamber (col.5, lines 54-56 and col.6, lines 19-32).

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to claim 4 and further in view of Vera et al (U.S.P.N. 6,440,364).

With respect to claim 5, the Popescu reference fails to teach evacuating to a pressure of 1 to 3 inches of mercury; however, the Vera reference teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Popescu reference by evacuating to between 1 to 3 inches of mercury as taught by the Vera reference in order to effectively remove air from the chamber and the package (col.3, lines 44-46).

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to claim 3 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

With respect to claim 7, the Popescu reference fails to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas; however, the Kolstad reference teaches

pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Popescu reference by including the pulsing process of the Kolstad reference in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (col.5, lines 30-41) for more efficient sterilization of the contents.

10. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) in view of Vera et al (U.S.P.N. 6,440,364) as applied to claim 5 and further in view of Stewart et al (U.S.P.N. 5,882,590).

With respect to claim 9, both the Popescu reference and the Vera reference fail to teach the use of real-time monitor of the concentration of ethylene oxide gas; however, the Stewart reference discloses the use of a real-time monitor for the concentration of ethylene oxide gas (col.4, lines 19-21 and lines 38-40). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Popescu reference by including a real-time monitor for the concentration of ethylene oxide gas as taught by the Stewart reference in order to maintain the concentration levels within acceptable ranges for given time periods to assure that critical concentration parameter values have been met (col.4, lines 21-24).

With respect to claim 10, the Popescu reference teaches degassing the

items by evacuating the chamber, pressurizing the chamber with 29 inches of mercury with nitrogen and repeating the cycle (col.6, lines 19-35).

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) in view of Vera et al (U.S.P.N. 6,440,364) and Stewart et al (U.S.P.N. 5,882,590) as applied to claim 9 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

With respect to claim 11, the Popescu reference, the Vera reference and the Stewart reference all fail to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas; however, the Kolstad reference teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made modify the method of the Popescu reference by including the pulsing process of the Kolstad reference in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (col.5, lines 30-41) for more efficient sterilization of the contents.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Green (U.S.P.N. 5,702,669) reference teaches injecting ethylene oxide then further adding nitrogen gas. The Johnson (U.S.P.N. 4,971,761) reference, the Childers et al (U.S.P.N. 5,492,672) reference and the

Conviser (U.S.P.N. 6,132,679) are all in the art of ethylene oxide sterilization and teach features similar to the instant claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, RICHARD D. CRISPINO can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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